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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|-----------------------|---------------------|------------------|
| 10/019,380 | 12/27/2001 | Frans Eduard Janssens | JANS-0026 | 6297 |

7590 07/14/2003

Philip S Johnson
Johnson & Johnson
One Johnson & Johnson Plaza
New Brunswick, NJ 08933-7003

EXAMINER

HABTE, KAHSAY

ART UNIT

PAPER NUMBER

1624

DATE MAILED: 07/14/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|----------------------|-----------------|
| Office Action Summary | Application N | Applicant(s) |
| | 10/019,380 | JANSSENS ET AL. |
| | Examiner | Art Unit |
| | Kahsay Habte, Ph. D. | 1624 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- If Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 6/17/03.

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 12-14, 16 and 17 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-11, 15 and 18-22 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121..

Attachment(s)

1) Notice of References Cited (PTO-892)

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____

4) Interview Summary (PTO-413) Paper No(s) _____

5) Notice of Informal Patent Application (PTO-152)

6) Other: _____

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DETAILED ACTION

1. Claims 1-22 are pending.

Election/Restriction

2. Applicant's election with traverse of Group V, Claims 1-11 (in part), 15 (in part) and 18-21 (in part) in Paper No. 9 is acknowledged. The traversal is on the ground(s) that the groups of inventions are related to a single general inventive concept, and thus the lack of unity is improper. The examiner disagrees with applicants. The technical features of Groups I-IX differ one from the other. For example, the special technical feature of benzimidazoles $\{-a^1=a^2-a^3=a^4-\text{ is (a-1)}\}$ is different from the special technical feature of monoazines fused to imidazoles $\{-a^1=a^2-a^3=a^4-\text{ is (a-2), (a-3), (a-4 or (a-5)}\}$. There is no common special technical feature among said inventions. The special technical feature of substituent Q attached to benzoimidazoles or Q attached to monoazines fused to imidazoles are also different one from the other. Note that Q also has special technical features, thus, azepine attached to benzoimidazoles is different than azepine attached to monoazines fused to imidazoles.

The traversal is also on the ground that no lack of unity was made in the international phase. This is not found persuasive because the United States Patent and Trademark Office is *not* bound by the lack of unity determination by another International Searching Authority. MPEP 1875 states that whether or not the question of unity of invention has been raised by the International Searching Authority, it may be considered by the examiner when serving as an authorized officer of the International

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Preliminary Examining Authority. Thus, the Examiner is *not* bound by any previous determination made. In addition, 37 C.F.R. 1.484 indicates that the international preliminary examination is a non-binding opinion. Finally, 37 C.F.R. 1.499 states that, if the Examiner finds that a national stage application lacks unity of invention under 37 C.F.R. 1.475, the Examiner may in an Office action require the applicant in the response to that action to elect the invention to which the claims shall be restricted. Thus, the determination of lack of unity is proper under the PCT treaty.

In regard to the argument that Groups I–IX do not cover all of the subject matter, the examiner disagrees with applicants. During a telephone conversation with Ms. Wendy Choi on June 3, 2003, the examiner indicates that Q = non-heterocyclic ring will include b-1- b3, b-4 when Y1 is C, and b-5 and b-7 when Y1 is C.

Note that Group IX is drawn to others include metal complex, quaternary amine, N-oxide, any heterocyclic ring in b4, e.g. Y1 = N and u =1-2 etc). "Others" will include compounds that don't fall into Groups I-VIII.

The requirement is still deemed proper and is therefore made FINAL.

3. The claims are drawn to multiple inventions for reasons set forth in the restriction requirement. The claims are examined only to the extent that they read on the elected invention. Cancellation of the non-elected subject matter is recommended in response to this Office Action.

Abstract

4. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. There has been recited a method of treating viral infection in general, but the specification is not enabled for such a scope. Viral infection is very broad, since the origin and nature viral infections vary one from the other. Viral infections can be categorized in 4 subgroups:

Slow viral infection is viral infections in which the infectious agents gradually increase in number over a very long period of time during which no significant symptoms are seen. Examples include AIDS (caused by HIV-1 and HIV-2) and certain lentiviruses that cause tumors in animals. Although not viruses, prions also cause slow infections.

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Acute virus infection is a viral infection of relatively short duration with rapid recovery.

Most viruses that infect humans, such as those that cause routine respiratory infections (e.g., cold viruses, influenza viruses) and gastrointestinal infections (e.g., Rotaviruses, Norwalk virus), cause acute infections.

Chronic viral infection is a viral infection where the virus can be demonstrated in the body at all times and the disease may be present or absent for an extended period of time. Examples include hepatitis B (caused by HBV) and hepatitis C (caused by HCV).

Latent viral infection is a viral infection where the virus remains in equilibrium with the host for long periods of time before symptoms again appear, but the actual viruses cannot be detected until reactivation of the disease occurs. Examples include infections caused by HSV-1 (fever blisters), HSV-2 (genital herpes), and VZV (chickenpox-shingles).

Since viral infections are extremely diverse in nature, it is impossible to treat all viral infections.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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Claims 1-11, 15 and 18-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

- a. Claim 1 and claims dependent thereon are rejected because the he phrase "wherein =Z is =O, =CH-C(=O)-NR^{5a}R^{5b}, .." is not clear. What is the significance of the double bond in front of variable Z? Does applicants intend to claim ==O or just =O? If the latter is true, applicants have to delete the double bonds from the definition of variable Z. It is recommended that the claim reads "wherein Z is O, CH-C(=O)-NR^{5a}R^{5b}, CH₂.." to overcome the rejection.
- b. In claim 8, "compound 75" is redundant since applicants recited the compound.
- c. In claim 8, the nomenclature of species includes [(A), (S)] or [(B), (S)], but it is unclear what "A" and "B" represent? What are the notations [(A)..] or [(B)..] represent in the nomenclature?

Conclusion

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kahsay Habte, Ph. D. whose telephone number is (703) 308-4717. The examiner can normally be reached on M-F (9.00AM- 5:30PM).

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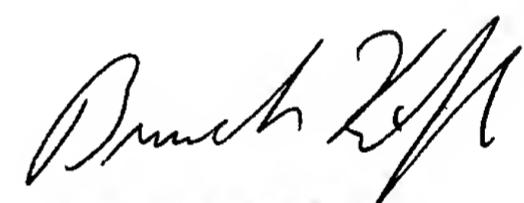
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

Kahsay Habte, Ph. D.
Examiner
Art Unit 1624

KH
July 11, 2003


Mukund J. Shah
Supervisory Patent Examiner
Art Unit 1624


BRUCK KIFLE, PH.D.
PRIMARY EXAMINER